REMARKS

Claims 1-5 are pending in this application. Claim 1 has been rejected. Claims 2-5 have been canceled. Claim 1 has been amended. No new matter has been added by this amendment.

I. Election/Restriction

The Examiner has deemed the restriction requirement proper and therefore, final. Claims 2-5 have been canceled in this paper in accordance with the making final of the restriction requirement.

II. Rejection of Claim 1 under 35 U.S.C. §112, first paragraph

The Examiner has rejected claim 1 under 35 U.S.C. §112, first paragraph. It is suggested that claim 1 contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to make or use the invention.

In accordance with the comments provided by the Examiner, the Applicants have amended claim 1 to clarify that the genotype at the -308 locus of the TNFα gene is associated with the

identification of CAP, as supported throughout the specification and particularly at page 6, lines 11-12, 25-26 and Example 1.

Further, the Examiner suggests that there is no teaching in the specification of a polymorphism in any non-human patient. Applicants disagree with this rejection.

However, in an earnest effort to facilitate prosecution of this application, claim 1 has been amended to recite a human patient. Support for this amendment can be found throughout the specification and at Example 1.

It is further suggested that performing PCR requires hybridization and primer extension reactions. It is suggested that the specification is silent as to how art recognized difficulties are to be overcome. Applicants respectfully disagree.

As taught at page 5, line 22 through page 6, determination of whether a TNFα gene contains the GA or AA genotype at position -308 may be determined by a number of methods known to those of skill in the art. Examples include PCR amplification and restriction enzyme digestion. As set forth in the specification at page 6, lines 6-8, PCR techniques are taught in EP-A-0200362 and EP-A-0201 184. Single strand mapping can also be used to

determine whether the TNFα gene is the risk or non-risk for (A allele at the -308 site).

Claim 1 has been yet further rejected as failing to comply with the written description requirement. It is suggested that the claim contains subject matter which was not described in the specification in such a way as to reasonably convey to one of skill in the art that the inventor at the time the invention was filed had possession of the claimed invention. It is also suggested that the specification fails to find an adequate written description of the assay including the specific starting materials and the reaction conditions to suggest that the Applicant was in possession of the assay at the time of filing. Applicants respectfully disagree.

As set forth in MPEP §2164.08, all questions of enablement are evaluated against the claimed subject matter. The focus of the examination inquiry is whether everything within the scope of the claim is enabled. The Federal Circuit has repeatedly held that "the specification must teach those skilled in the art how to make and use the full scope of the claimed invention without 'undue experimentation'." *In re Wright,* 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993). Nevertheless, not everything necessary to practice the invention need be disclosed. In fact,

what is well-known is best omitted. *In re Buchner*, 929 F.2d 660, 661, 18 USPQ2d 1331, 1332 (Fed. Cir. 1991). All that is necessary is that one skilled in the art be able to practice the claimed invention, given the level of knowledge and skill in the art. Further the scope of enablement must only bear a "reasonable correlation" to the scope of the claims. See, e.g., *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970). As concerns the breadth of a claim relevant to enablement, the only relevant concern should be whether the scope of enablement provided to one skilled in the art by the disclosure is commensurate with the scope of protection sought by the claims. *In re Moore*, 439 F.2d 1232, 1236, 169 USPQ 236, 239 (CCPA 1971). See also *Plant Genetic Sys., N.V. v. DeKalb Genetics Corp.*, 315 F.3d 1335, 1339, 65 USPQ2d 1452, 1455 (Fed. Cir. 2003) (alleged "pioneer status" of invention irrelevant to enablement determination).

Further, as recited at MPEP §2164 one does not look to the claims but to the specification to find out how to practice the claimed invention. *W.L. Gore & Assoc., Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1558, 220 USPQ 303, 316-17 (Fed. Cir. 1983);

Claim 1 has been amended to clarify the invention as set forth *supra*. As is clearly taught throughout the specification particularly at page 6, lines 308, PCR techniques are well known in the art and it would be within the ambit of a person of ordinary skill in the art to identify primers for amplifying a suitable section of the applicable exon of the TNFα gene. Further, Applicants have given two examples of references which teach suitable PCR techniques, namely EP-A-0200362 and EP-A-0201 184. Thus, Applicants respectfully submit that one skilled in the art would be able to practice the claimed invention, given the level of knowledge and skill in the art and the teachings of the present invention.

Withdrawal of these rejections is respectfully requested.

III. Double Patenting

The Examiner has rejected claim 1 under 35 U.S.C. 101 as claiming the same invention as that of claim 1 of prior U.S. Patent No. 6, 294,339. Applicants respectfully disagree.

Applicants have amended claim 1 to clarify the invention and highlight the differences between this claim, namely that the method comprises determining the genotype at the -308 locus of

the TNFα gene in a human patient; and identifying increased risk of death from CAP based on the genotype.

Withdrawal of this rejection is respectfully requested.

IV. Conclusion

Applicants believe that the foregoing comprises a full and complete response to the Office Action of record. Accordingly, favorable reconsideration and subsequent allowance of the pending claims is earnestly solicited.

Respectfully submitted,

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